SCHEDULING STATUS: S4

1. NAME OF THE MEDICINE

COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE 10 micrograms/dose concentrate for dispersion for injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE is a multidose vial with an orange cap and must be diluted before use.

One vial (1,3 mL) contains 10 doses of 0,2 mL after dilution, see sections 4.2 and 6.6.

One dose (0,2 mL) contains 10 micrograms of tozinameran, a COVID-19 mRNA vaccine (embedded in lipid nanoparticles).

Tozinameran is a single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free *in vitro* transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2.

Contains sugar (sucrose) and sodium chloride.

Excipients with known effect

Each 0,2 mL dose contains 10,3 mg sucrose and 0,9 mg sodium chloride.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Concentrate for dispersion for injection (sterile concentrate).

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The vaccine is a white to off-white frozen dispersion (pH: 6,9 – 7,9).

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE 10 micrograms/dose concentrate for dispersion for injection is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in children aged 5 to 11 years.

The use of this vaccine should be in accordance with official recommendations.

4.2 Posology and method of administration

Posology

Children 5 to 11 years of age (i.e. 5 to less than 12 years of age)

COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE 10 micrograms/dose is administered intramuscularly after dilution as a primary course of 2 doses (0,2 mL each). It is recommended to administer the second dose 3 weeks after the first dose (see sections 4.4 and 5.1).

Severely immunocompromised aged 5 years and older

A third primary course dose may be administered intramuscularly at least 28 days after the second dose to individuals who are severely immunocompromised (see section 4.4).

Interchangeability

The interchangeability of COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE with COVID-19 vaccines from other manufacturers to complete the vaccination course has not been established. Individuals who have received a dose of COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE should continue to receive COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE to complete the primary course.

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COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE 10 micrograms/dose should be used only for children 5 to 11 years of age

Paediatric population

The safety and efficacy of COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE in children aged less than 5 years have not yet been established.

Method of administration

COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE 10 micrograms/dose concentrate for dispersion for injection should be administered intramuscularly after dilution (see section 6.6).

After dilution, vials of COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE contain 10 doses of 0,2 mL of vaccine. In order to extract 10 doses from a single vial, low dead-volume syringes and/or needles should be used. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres. If standard syringes and needles are used, there may not be sufficient volume to extract 10 doses from a single vial. Irrespective of the type of syringe and needle:

- Each dose must contain 0,2 mL of vaccine
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0,2 mL, discard the vial and any excess volume
- Do not pool excess vaccine from multiple vials

The preferred site is the deltoid muscle of the upper arm.

Do not inject the vaccine intravascularly, subcutaneously or intradermally.

The vaccine should not be mixed in the same syringe with any other vaccines or medicines.

For precautions to be taken before administering the vaccine, see section 4.4.

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For instructions regarding thawing, handling and disposal of the vaccine, see section 6.6.

4.3 Contraindications

Hypersensitivity to COVID-19 mRNA vaccine (nucleoside modified) or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Traceability

In order to improve the traceability of biological medicines, the name and the batch number of the administered medicine should be clearly recorded.

General recommendations

Hypersensitivity and anaphylaxis

Events of anaphylaxis have been reported. Appropriate medical treatment and supervision should always be readily available in case of an anaphylactic reaction following the administration of the vaccine.

Close observation for at least 15 minutes is recommended following vaccination. No further dose of the vaccine should be given to those who have experienced anaphylaxis after a prior dose of COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE.

Myocarditis and pericarditis

There is an increased risk of myocarditis and pericarditis following vaccination with COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE. These conditions can develop within just a few days after vaccination, and have primarily occurred within 14 days. They have been observed more often after the second vaccination, and more often in younger males (see section 4.8). Available data suggest that the course of myocarditis and pericarditis following vaccination is not different from myocarditis or pericarditis in general.

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Medical practitioners should be alert to the signs and symptoms of myocarditis and pericarditis. Vaccinees (including parents or caregivers) should be instructed to seek immediate medical attention if they develop symptoms indicative of myocarditis or pericarditis such as (acute and persisting) chest pain, shortness of breath, or palpitations following vaccination.

Medical practitioners should consult guidance and/or specialists to diagnose and treat this condition.

The risk of myocarditis after a third dose of COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE has not yet been characterised.

Anxiety-related reactions

Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions (e.g. dizziness, palpitations, increases in heart rate, alterations in blood pressure, paraesthesia, hypoaesthesia and sweating) may occur in association with the vaccination process itself. Stress-related reactions are temporary and resolve on their own. Individuals should be advised to bring symptoms to the attention of the vaccination provider for evaluation. It is important that precautions are in place to avoid injury from fainting.

Concurrent illness

Vaccination should be postponed in individuals suffering from acute severe febrile illness or acute infection. The presence of a minor infection and/or low-grade fever should not delay vaccination.

Thrombocytopenia and coagulation disorders

The vaccine should be given with caution in individuals receiving anticoagulant therapy or those with thrombocytopenia or any coagulation disorder (such as haemophilia) because bleeding or bruising may occur following an intramuscular administration in these individuals.

Immunocompromised individuals

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The efficacy and safety of the vaccine has not been assessed in immunocompromised individuals, including those receiving immunosuppressant therapy. The efficacy of COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE may be lower in immunocompromised individuals.

The recommendation to consider a third dose in severely immunocompromised individuals is based on limited serological evidence from a case series in the literature from the clinical management of patients with iatrogenic immunocompromisation after solid organ transplantation (see section 4.2).

Duration of protection

The duration of protection afforded by the vaccine is unknown as it is still being determined by ongoing clinical trials.

Limitations of vaccine effectiveness

Vaccination with COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE may not protect all vaccine recipients. Individuals may not be fully protected until 7 days after their second dose of vaccine.

Excipients

COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE contains less than 1 mmol sodium (0,9 mg) per dose, that is to say essentially ‘sodium-free’.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies have been performed.

Concomitant administration of COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE with other vaccines has not been studied.

4.6 Fertility, pregnancy and lactation

Pregnancy

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A large amount of observational data from pregnant women vaccinated with COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE during the second and third trimester have not shown an increase in adverse pregnancy outcomes. While data on pregnancy outcomes following vaccination during the first trimester are presently limited, no increased risk for miscarriage has been seen. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/foetal development, parturition or post-natal development (see section 5.3). COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE can be used during pregnancy.

Breastfeeding

No effects on the breastfed newborn/infant are anticipated since the systemic exposure of breastfeeding woman to COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE is negligible. Observational data from women who were breastfeeding after vaccination have not shown a risk for adverse effects in breastfed newborns/infants. COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE can be used during breastfeeding.

Fertility

Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3).

4.7 Effects on ability to drive and use machines

COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE has no or negligible influence on the ability to drive and use machines. However, some of the effects mentioned under section 4.8 may temporarily affect the ability to drive or use machines.

4.8 Undesirable effects

Summary of the safety profile

Children 5 to 11 years of age (i.e. 5 to less than 12 years of age) – after 2 doses

In Study 3, a total of 1,518 children 5 to 11 years of age received at least 1 dose of COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE 10 mcg and a total of 750 children 5 to 11 years of age

received placebo. At the time of the analysis of Study 3 Phase 2/3 with data up to the cut-off date of 6 September 2021, 2,158 (95,1 %) (1,444 COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE 10 mcg and 714 placebo) children have been followed for at least 2 months after the second dose of COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE 10 mcg. An analysis of Study 3 Phase 2/3 adverse event data also included another 2,379 participants [1,591 COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE 10 mcg and 788 placebo], of whom 71,2 % had a follow-up period for at least 2 weeks after Dose 2 up to the cut-off date of 8 October 2021. The safety evaluation in Study 3 is ongoing.

The overall safety profile of COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE in participants 5 to 15 years of age was similar to that seen in participants 16 years of age and older. The most frequent adverse reactions in children 5 to 11 years of age were injection site pain (> 80 %), fatigue (> 50 %), headache (> 30 %), injection site redness and swelling (> 20 %), myalgia and chills (> 10 %).

Adolescents 12 to 15 years of age – after 2 doses

In an analysis of long-term safety follow-up in Study 2, 2,260 adolescents (1,131 COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE 30 mcg and 1,129 placebo) were 12 to 15 years of age. Of these, 1,559 adolescents (786 COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE and 773 placebo) have been followed for at least ≥ 4 months after the second dose of COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE. The safety evaluation in Study 2 is ongoing.

The overall safety profile of COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE in adolescents 12 to 15 years of age was similar to that seen in participants 16 years of age and older. The most frequent adverse reactions in adolescents 12 to 15 years of age that received 2 doses were injection site pain (> 90 %), fatigue and headache (> 70 %), myalgia and chills (> 40 %), arthralgia and pyrexia (> 20 %).

Participants 16 years of age and older – after 2 doses

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In Study 2, a total of 22,026 participants 16 years of age or older received at least 1 dose of COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE 30 mcg and a total of 22,021 participants 16 years of age or older received placebo (including 138 and 145 adolescents 16 and 17 years of age in the vaccine and placebo groups, respectively). A total of 20,519 participants 16 years of age or older received 2 doses of COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE.

At the time of the analysis of Study 2 with a data cut-off of 13 March 2021 for the placebo-controlled blinded follow-up period up to the participants' unblinding dates, a total of 25,651 (58,2 %) participants (13,031 COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE and 12,620 placebo) 16 years of age and older were followed up for ≥ 4 months after the second dose. This included a total of 15,111 (7,704 COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE and 7,407 placebo) participants 16 to 55 years of age and a total of 10,540 (5,327 COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE and 5,213 placebo) participants 56 years of age and older.

The most frequent adverse reactions in participants 16 years of age and older that received 2 doses were injection site pain (> 80 %), fatigue (> 60 %), headache (> 50 %), myalgia (> 40 %), chills (> 30 %), arthralgia (> 20 %), pyrexia and injection site swelling (> 10 %) and were usually mild or moderate in intensity and resolved within a few days after vaccination. A slightly lower frequency of reactogenicity events was associated with greater age.

The safety profile in 545 participants 16 years of age and older receiving COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE, that were seropositive for SARS-CoV-2 at baseline, was similar to that seen in the general population.

Participants 16 years of age and older – after booster dose

A subset from Study 2 Phase 2/3 participants of 306 adults 18 to 55 years of age who completed the original 2-dose course, received a booster dose of COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE approximately 6 months (range of 4,8 to 8,0 months) after receiving Dose 2.

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The overall safety profile for the booster dose was similar to that seen after 2 doses. The most frequent adverse reactions in participants 18 to 55 years of age were injection site pain (> 80 %), fatigue (> 60 %), headache (> 40 %), myalgia (> 30 %), chills and arthralgia (> 20 %).

In Study 4, a placebo-controlled booster study, participants 16 years of age and older recruited from Study 2 received a booster dose of COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE (5,081 participants), or placebo (5,044 participants) at least 6 months after the second dose of COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE. Overall, participants who received a booster dose, had a median follow-up time of 2,5 months after the booster dose to the cut-off date (5 October 2021). No new adverse reactions of COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE were identified.

Booster dose following primary vaccination with another authorised COVID-19 vaccine

In 5 independent studies on the use of a COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE booster dose in individuals who had completed primary vaccination with another authorized COVID-19 vaccine (heterologous booster dose), no new safety issues were identified.

Tabulated list of adverse reactions from clinical studies and post-authorisation in individuals 5 years of age and older

Adverse reactions observed during clinical studies are listed below according to the following frequency categories: Very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1 000 to < 1/100), rare (≥ 1/10 000 to < 1/1 000), very rare (< 1/10 000), not known (cannot be estimated from the available data).

Table 1: Adverse reactions from COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE clinical trials in individuals 5 years of age and older

System organ class	**Frequency**	**Adverse reaction**
Blood and lymphatic system disorders	Uncommon	Lymphadenopathy[a]

Immune system disorders	Uncommon	Hypersensitivity reactions (e.g. rash, pruritus, urticaria[b], angioedema[b])
	Not known	Anaphylaxis
Metabolism and nutrition disorders	Uncommon	Decreased appetite
Psychiatric disorders	Uncommon	Insomnia
Nervous system disorders	Very common	Headache
	Uncommon	Lethargy
	Rare	Acute peripheral facial paralysis[c]
Gastrointestinal disorders	Common	Nausea
Skin and subcutaneous tissue disorders	Uncommon	Hyperhidrosis, night sweats
Musculoskeletal and connective tissue disorders	Very common	Arthralgia, myalgia
	Uncommon	Pain in extremity[d]
General disorders and administration site conditions	Very common	Injection site pain, fatigue, chills, pyrexia[e], injection site swelling
	Common	Injection site redness[f]
	Uncommon	Asthenia, malaise, injection site pruritus

a. A higher frequency of lymphadenopathy (5,2 % vs 0,4 %) was observed in participants receiving a booster dose (third dose) compared to participants receiving 2 doses.

b. The frequency category for urticaria and angioedema was rare.

c. Through the clinical trial safety follow-up period to 14 November 2020, acute peripheral facial paralysis (or palsy) was reported by four participants in the COVID-19 mRNA vaccine group. Onset

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was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of acute peripheral facial paralysis (or palsy) were reported in the placebo group.

d. Refers to vaccinated arm.

e. A higher frequency of pyrexia was observed after the second dose compared to the first dose.

f. Injection site redness occurred at a higher frequency (very common) in children 5 to 11 years of age.

Post-marketing side effects

Nervous system disorders: Paraesthesia, hypoaesthesia

Cardiac disorders: Myocarditis, pericarditis

Gastrointestinal disorders: Diarrhoea, vomiting

Skin and subcutaneous tissue disorder: Erythema multiforme

General disorders and administration site conditions: Extensive swelling of vaccinated limb, facial swelling (facial swelling in vaccine recipients with a history of injection of dermatological fillers)

Description of selected adverse reactions

Myocarditis

The increased risk of myocarditis after vaccination with COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE is highest in younger males (see section 4.4).

Two large European pharmacoepidemiological studies have estimated the excess risk in younger males following the second dose of COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE. One study showed that in a period of 7 days after the second dose there were about 0,265 (95 % CI 0,255 – 0,275) extra cases of myocarditis in 12-29 year old males per 10,000 compared to unexposed persons. In another study, in a period of 28 days after the second dose there were 0,57 [95 % CI 0,39 – 0,75] extra cases of myocarditis in 16 - 24 year old males per 10,000 compared to unexposed persons.

Reporting of suspected adverse reactions

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Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications:
https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose

Overdose data is available from 52 study participants included in the clinical trial that due to an error in dilution received 58 micrograms of COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE. The vaccine recipients did not report an increase in reactogenicity or adverse reactions.

In the event of overdose, monitoring of vital functions and possible symptomatic treatment is recommended.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: vaccines, other viral vaccines, ATC code: J07BX03

Mechanism of action

The nucleoside-modified messenger RNA in COVID-19 mRNA vaccine (tozinameran) is formulated in lipid nanoparticles, which enable delivery of the non-replicating RNA into host cells to direct transient expression of the SARS-CoV-2 S antigen. The mRNA codes for membrane-anchored, full-length S with two-point mutations within the central helix. Mutation of these two amino acids to proline locks S in an antigenically preferred prefusion conformation. The vaccine elicits both neutralising antibody and cellular immune responses to the spike (S) antigen, which may contribute to protection against COVID-19.

Efficacy

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Study 2 is a multicentre, multinational, Phase 1/2/3 randomised, placebo-controlled, observer-blind dose-finding, vaccine candidate selection and efficacy study in participants 12 years of age and older. Randomisation was stratified by age: 12 to 15 years of age, 16 to 55 years of age, or 56 years of age and older, with a minimum of 40 % of participants in the ≥ 56-year stratum. The study excluded participants who were immunocompromised and those who had previous clinical or microbiological diagnosis of COVID-19. Participants with pre-existing stable disease, defined as disease not requiring significant change in therapy or hospitalisation for worsening disease during the 6 weeks before enrolment, were included as were participants with known stable infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV) or hepatitis B virus (HBV).

Efficacy in participants 16 years of age and older – after 2 doses

In the Phase 2/3 portion of Study 2, based on data accrued through 14 November 2020, approximately 44,000 participants were randomised equally and were to receive 2 doses of COVID-19 mRNA vaccine or placebo. The efficacy analyses included participants that received their second vaccination within 19 to 42 days after their first vaccination. The majority (93,1 %) of vaccine recipients received the second dose 19 days to 23 days after Dose 1. Participants are planned to be followed for up to 24 months after Dose 2, for assessments of safety and efficacy against COVID-19. In the clinical study, participants were required to observe a minimum interval of 14 days before and after administration of an influenza vaccine in order to receive either placebo or COVID-19 mRNA vaccine. In the clinical study, participants were required to observe a minimum interval of 60 days before or after receipt of blood/plasma medicines or immunoglobulins within through conclusion of the study in order to receive either placebo or COVID-19 mRNA vaccine.

The population for the analysis of the primary efficacy endpoint included 36,621 participants 12 years of age and older (18,242 in the COVID-19 mRNA vaccine group and 18,379 in the placebo group) who did not have evidence of prior infection with SARS-CoV-2 through 7 days after the second dose. In addition, 134 participants were between the ages of 16 to 17 years of age (66 in the COVID-19 mRNA vaccine group and 68 in the placebo group) and 1,616 participants 75 years of age and older (804 in the COVID-19 mRNA vaccine group and 812 in the placebo group).

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At the time of the primary efficacy analysis, participants had been followed for symptomatic COVID-19 for in total 2,214 person-years for the COVID-19 mRNA vaccine and in total 2,222 person-years in the placebo group.

There were no meaningful clinical differences in overall vaccine efficacy in participants who were at risk of severe COVID-19 including those with 1 or more comorbidities that increase the risk of severe COVID-19 (e.g., asthma, body mass index (BMI) ≥ 30 kg/m^2, chronic pulmonary disease, diabetes mellitus, hypertension).

The vaccine efficacy information is presented in Table 2.

Table 2: Vaccine efficacy – First COVID-19 occurrence from 7 days after Dose 2, by age subgroup – participants without evidence of infection prior to 7 days after Dose 2 – evaluable efficacy (7 days) population

First COVID-19 occurrence from 7 days after Dose 2 in participants without evidence of prior SARS-CoV-2 infection*			
Subgroup	**COVID-19 mRNA Vaccine N[a] = 18,198 Cases n1[b] Surveillance time[c] (n2[d])**	**Placebo N[a] = 18,325 Cases n1[b] Surveillance time[c] (n2[d])**	**Vaccine efficacy % (95 % CI)[e]**
All participants	8 2,214 (17,411)	162 2,222 (17,511)	95,0 (90,0, 97,9)
16 to 64 years	7 1,706 (13,549)	143 1,710 (13,618)	95,1 (89,6, 98,1)

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65 years and older	1 0,508 (3,848)	19 0,511 (3,880)	94,7 (66,7, 99,9)
65 to 74 years	1 0,406 (3,074)	14 0,406 (3,095)	92,9 (53,1, 99,8)
75 years and older	0 0,102 (774)	5 0,106 (785)	100,0 (-13,1, 100,0)

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 [*Case definition: (at least 1 of) fever, new or increased cough, new or increased shortness of breath, chills, new or increased muscle pain, new loss of taste or smell, sore throat, diarrhoea or vomiting.]

* Participants who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by nucleic acid amplification tests (NAAT) [nasal swab] at Visits 1 and 2) and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

a. N = Number of participants in the specified group.

b. n1 = Number of participants meeting the endpoint definition.

c. Total surveillance time in 1,000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.

d. n2 = Number of participants at risk for the endpoint.

e. Two-sided confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted to the surveillance time. CI not adjusted for multiplicity.

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Efficacy of COVID-19 mRNA vaccine in preventing first COVID-19 occurrence from 7 days after Dose 2 compared to placebo was 94,6 % (95 % confidence interval of 89,6 % to 97,6 %) in participants 16 years of age and older with or without evidence of prior infection with SARS-CoV-2.

Additionally, subgroup analyses of the primary efficacy endpoint showed similar efficacy point estimates across genders, ethnic groups, and participants with medical comorbidities associated with high risk of severe COVID-19.

Updated efficacy analyses were performed with additional confirmed COVID-19 cases accrued during blinded placebo-controlled follow-up representing up to 6 months after Dose 2 in the efficacy population.

The updated vaccine efficacy information is presented in Table 3.

Table 3: Vaccine efficacy – First COVID-19 occurrence from 7 days after Dose 2, by age subgroup – participants without evidence of prior SARS-CoV-2 infection* prior to 7 days after Dose 2 – evaluable efficacy (7 days) population during the placebo-controlled follow-up period

Subgroup	COVID-19 mRNA Vaccine N[a]=20,998 Cases n1[b] Surveillance time[c] (n2[d])	Placebo N[a]=21,096 Cases n1[b] Surveillance time[c] (n2[d])	Vaccine efficacy % (95 % CI[e])
All participants[f]	77 6,247 (20,712)	850 6,003 (20,713)	91,3 (89,0, 93,2)
16 to 64 years	70 4,859 (15,519)	710 4,654 (15,515)	90,6 (87,9, 92,7)

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65 years and older	7 1,233 (4192)	124 1,202 (4226)	94,5 (88,3, 97,8)
65 to 74 years	6 0,994 (3350)	98 0,966 (3379)	94,1 (86,6, 97,9)
75 years and older	1 0,239 (842)	26 0,237 (847)	96,2 (76,9, 99,9)

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhoea; vomiting).

* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

a. N = Number of participants in the specified group.

b. n1 = Number of participants meeting the endpoint definition.

c. Total surveillance time in 1,000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.

d. n2 = Number of participants at risk for the endpoint.

e. Two-sided 95 % confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted to the surveillance time.

f. Included confirmed cases in participants 12 to 15 years of age: 0 in the COVID-19 mRNA Vaccine group 16 in the placebo group.

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In the updated efficacy analysis, efficacy of COVID-19 mRNA Vaccine in preventing first COVID-19 occurrence from 7 days after Dose 2 compared to placebo was 91,1 % (95 % CI of 88,8 % to 93,0 %) in participants in the evaluable efficacy population with or without evidence of prior infection with SARS-CoV-2.

Additionally, the updated efficacy analyses by subgroup showed similar efficacy point estimates across sexes, ethnic groups, geography and participants with medical comorbidities and obesity associated with high risk of severe COVID-19.

Efficacy against severe COVID-19

Updated efficacy analyses of secondary efficacy endpoints supported benefit of the COVID-19 mRNA Vaccine in preventing severe COVID-19.

As of 13 March 2021, vaccine efficacy against severe COVID-19 is presented only for participants with or without prior SARS-CoV-2 infection (Table 4) as the COVID-19 case counts in participants without prior SARS-CoV-2 infection were the same as those in participants with or without prior SARS-CoV-2 infection in both the COVID-19 mRNA Vaccine and placebo groups.

Table 4: Vaccine efficacy – First severe COVID-19 occurrence in participants with or without prior SARS-CoV-2 infection based on the Food and Drug Administration (FDA)* or after Dose 1 or from 7 days after Dose 2 in the placebo-controlled follow-up

	COVID-19 mRNA Vaccine Cases n1[a] Surveillance time (n2[b])	**Placebo Cases n1[a] Surveillance time (n2[b])**	**Vaccine efficacy % (95 % CI[c])**
After Dose 1[d]	1 8,439[e] (22,505)	30 8,288[e] (22,435)	96,7 (80,3, 99,9)

7 days after Dose 2[f]	1 6,522[g] (21,649)	21 6,404[g] (21,730)	95,3 (70,9, 99,9)

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhoea; vomiting).

* Severe illness from COVID-19 as defined by FDA is confirmed COVID-19 and presence of at least 1 of the following:

- Clinical signs at rest indicative of severe systemic illness (respiratory rate ≥ 30 breaths per minute, heart rate ≥ 125 beats per minute, saturation of oxygen ≤ 93 % on room air at sea level, or ratio of arterial oxygen partial pressure to fractional inspired oxygen < 300 mm Hg);
- Respiratory failure [defined as needing high-flow oxygen, non-invasive ventilation, mechanical ventilation or extracorporeal membrane oxygenation (ECMO)]
- Evidence of shock (systolic blood pressure < 90 mm Hg, diastolic blood pressure < 60 mm Hg, or requiring vasopressors)
- Significant acute renal, hepatic, or neurologic dysfunction
- Admission to an Intensive Care Unit
- Death.

a. n1 = Number of participants meeting the endpoint definition.

b. n2 = Number of participants at risk for the endpoint.

c. Two-side confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted to the surveillance time.

d. Efficacy assessed based on the Dose 1 all available efficacy (modified intention-to-treat) population that included all randomised participants who received at least 1 dose of study intervention.

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e. Total surveillance time in 1,000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from Dose 1 to the end of the surveillance period.

f. Efficacy assessed based on the evaluable efficacy (7 Days) population that included all eligible randomised participants who receive all dose(s) of study intervention as randomised within the predefined window, have no other important protocol deviations as determined by the clinician.

g. Total surveillance time in 1,000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.

Efficacy and immunogenicity in adolescents 12 to 15 years of age – after 2 doses

In an initial analysis of Study 2 in adolescents 12 to 15 years of age (representing a median follow-up duration of >2 months after Dose 2) without evidence of prior infection, there were no cases in 1,005 participants who received the vaccine and 16 cases out of 978 who received placebo. The point estimate for efficacy is 100 % (95 % confidence interval 75,3; 100,0). In participants with or without evidence of prior infection there were 0 cases in the 1,119 who received vaccine and 18 cases in 1,110 participants who received placebo. This also indicates the point estimate for efficacy is 100 % (95 % confidence interval 78,1; 100,0).

Updated efficacy analyses were performed with additional confirmed COVID-19 cases accrued during blinded placebo-controlled follow-up, representing up to 6 months after Dose 2 in the efficacy population.

In the updated efficacy analysis of Study 2 in adolescents 12 to 15 years of age without evidence of prior infection, there were no cases in 1,057 participants who received the vaccine and 28 cases out of 1,030 who received placebo. The point estimate for efficacy is 100% (95% confidence interval 86.8, 100.0). In participants with or without evidence of prior infection there were 0 cases in the 1,119 who

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received vaccine and 30 cases in 1,109 participants who received placebo. This also indicates the point estimate for efficacy is 100% (95% confidence interval 87.5, 100.0).

In Study 2, an analysis of SARS-CoV-2 neutralising titres 1 month after Dose 2 was conducted in a randomly selected subset of participants who had no serological or virological evidence of past SARS-CoV-2 infection up to 1 month after Dose 2, comparing the response in adolescents 12 to 15 years of age (n=190) to participants 16 to 25 years of age (n=170).

The ratio of the geometric mean titres (GMT) in the 12 to 15 years of age group to the 16 to 25 years of age group was 1,76, with a 2-sided 95 % CI of 1,47 to 2,10. Therefore, the 1,5-fold non-inferiority criterion was met as the lower bound of the 2-sided 95 % CI for the geometric mean ratio [GMR] was > 0,67.

Efficacy and immunogenicity in children 5 to 11 years of age (i.e. 5 to less than 12 years of age) after 2 doses

Study 3 is a Phase 1/2/3 study comprised of an open-label vaccine dose-finding portion (Phase 1) and a multicentre, multinational, randomised, saline placebo-controlled, observer-blind efficacy portion (Phase 2/3) that has enrolled participants 5 to 11 years of age. The majority (94,4 %) of randomised vaccine recipients received the second dose 19 days to 23 days after Dose 1.

The descriptive vaccine efficacy results in children 5 to 11 years of age without evidence of prior SARS-CoV-2 infection are presented in Table 5. No cases of COVID-19 were observed in either the vaccine group or the placebo group in participants with evidence of prior SARS-CoV-2 infection.

Table 5: Vaccine efficacy – First COVID-19 occurrence from 7 days after Dose 2: Without evidence of infection prior to 7 days after Dose 2 – Phase 2/3 – Children 5 to 11 years of age evaluable efficacy population.

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First COVID-19 occurrence from 7 days after Dose 2 in children 5 to 11 years of age without evidence of prior SARS-CoV-2 infection*			
	COVID-19 mRNA Vaccine 10 mcg/dose N[a]=1305 Cases n1[b] Surveillance time[c] (n2[d])	**Placebo N[a]=663 Cases n1[b] Surveillance time[c] (n2[d])**	**Vaccine efficacy % (95 % CI)**
Children 5 to 11 years of age	3 0,322 (1273)	16 0,159 (637)	90,7 (67,7, 98,3)

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhoea; vomiting).

* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

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a. N = Number of participants in the specified group.

b. n1 = Number of participants meeting the endpoint definition.

c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.

d. n2 = Number of participants at risk for the endpoint.

In Study 3, an analysis of SARS-CoV-2 50 % neutralising titres (NT50) 1 month after Dose 2 in a randomly selected subset of participants demonstrated effectiveness by immunobridging of immune responses comparing children 5 to 11 years of age (i.e. 5 to less than 12 years of age) in the Phase 2/3 part of Study 3 to participants 16 to 25 years of age in the Phase 2/3 part of Study 2 who had no 50 serological or virological evidence of past SARS-CoV-2 infection up to 1 month after Dose 2, meeting the prespecified immunobridging criteria for both the geometric mean ratio (GMR) and the seroresponse difference with seroresponse defined as achieving at least 4-fold rise in SARS-CoV-2 NT50 from baseline (before Dose 1).

The GMR of the SARS-CoV-2 NT50 1 month after Dose 2 in children 5 to 11 years of age (i.e. 5 to less than 12 years of age) to that of young adults 16 to 25 years of age was 1,04 (2-sided 95 % CI: 0,93, 1,18). Among participants without prior evidence of SARS-CoV-2 infection up to 1 month after Dose 2, 99,2 % of children 5 to 11 years of age and 99,2 % of participants 16 to 25 years of age had a seroresponse at 1 month after Dose 2. The difference in proportions of participants who had seroresponse between the 2 age groups (children – young adult) was 0,0 % (2-sided 95 % CI: -2,0 %, 2,2 %). This information is presented in Table 6.

Table 6: Summary of geometric mean ratio for 50 % neutralising titre and difference in percentages of participants with seroresponse – comparison of children 5 to 11 years of age (Study 3) to participants 16 to 25 years of age (Study 2) – participants without evidence of

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infection up to 1 month after Dose 2 – immunobridging subset – Phase 2/3 – evaluable immunogenicity population.

		COVID-19 mRNA Vaccine			
		10 mcg/dose 5 to 11 years N[a]=264	30 mcg/dose 16 to 25 years N[a]=253	5 to 11 years/ 16 to 25 years	
	Time point[b]	GMT[c] (95 % CI[c])	GMT[c] (95% CI[c])	GMR[d] (95% CI[d])	Met immune-bridging objective[e] (Y/N)
Geometric mean 50 % neutral-lizing titer[f] (GMT[c])	1 month after Dose 2	1197,6 (1106,1, 1296,6)	1146.5 (1045,5, 1257,2)	1.04 (0,93, 1,18)	Y
	Time point[b]	**n[g] (%) (95 % CI[h])**	**n[g] (%) (95 % CI[h])**	**Difference %[i] (95 % CI[j])**	**Met immune-bridging objective[k] (Y/N)**
Sero-response rate (%) for 50 % neutral-lizing titer[f]	1 month after Dose 2	262 (99,2) (97,3, 99,9)	251 (99,2) (97,2, 99,9)	0,0 (-2,0, 2,2)	Y

Abbreviations: CI = confidence interval; GMR = geometric mean ratio; GMT = geometric mean titre; LLOQ = lower limit of quantitation; NAAT = nucleic acid amplification test; NT50 = 50 % neutralising titre; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Note: Participants who had no serological or virological evidence (up to 1-month post-Dose 2 blood sample collection) of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Dose

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1 visit and 1 month after Dose 2, SARS-CoV-2 not detected by NAAT [nasal swab] at Dose 1 and Dose 2 visits, and negative NAAT (nasal swab) at any unscheduled visit up to 1 month after Dose 2 blood collection) and had no medical history of COVID-19 were included in the analysis.

Note: Seroresponse is defined as achieving a ≥4-fold rise from baseline (before Dose 1). If the baseline measurement is below the LLOQ, a postvaccination assay result ≥4 × LLOQ is considered a seroresponse.

a. N = Number of participants with valid and determinate assay results before vaccination and at 1 month after Dose 2. These values are also the denominators used in the percentage calculations for seroresponse rates.
b. Protocol-specified timing for blood sample collection.
c. GMTs and 2-sided 95 % CIs were calculated by exponentiating the mean logarithm of the titres and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
d. GMRs and 2-sided 95 % CIs were calculated by exponentiating the mean difference of the logarithms of the titres (5 to 11 years of age minus 16 to 25 years of age) and the corresponding CI (based on the Student t distribution).
e. Immunobridging based on GMT is declared if the lower bound of the 2-sided 95 % CI for the GMR is greater than 0, 67 and the point estimate of the GMR is ≥ 0,8.
f. SARS-CoV-2 NT50 were determined using the SARS-CoV-2 mNeonGreen Virus Microneutralization Assay. The assay uses a fluorescent reporter virus derived from the USA_WA1/2020 strain and virus neutralisation are read on Vero cell monolayers. The sample NT50 is defined as the reciprocal serum dilution at which 50 % of the virus is neutralised.
g. n=Number of participants with seroresponse based on NT50 1 month after Dose 2.
h. Exact 2-sided CI based on the Clopper and Pearson method.
i. Difference in proportions, expressed as a percentage (5 to 11 years of age minus 16 to 25 years of age).
j. 2-Sided CI, based on the Miettinen and Nurminen method for the difference in proportions, expressed as a percentage.

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k. Immunobridging based on seroresponse rate is declared if the lower bound of the 2-sided 95 % CI for the seroresponse difference is greater than -10,0 %.

Paediatric population

See section 4.2.

5.2 Pharmacokinetic properties

Biodistribution results from a luciferase encoding modRNA formulated in the same LNP as BNT162b2, representative of the biodistribution of the modRNA LNP vaccine platform

After administration of an LNP-formulated luciferase-encoding modRNA to BALB/c mice by intramuscular (IM) injection of 1 µg each in the right and left hind leg (for a total of 2 µg), *in vivo* bioluminescence after injection of luciferin substrate was performed. Luciferase protein expression was detected at different timepoints at the site of injection and to a lesser extent, and more transiently (only seen at 6 hr post-injection), in the liver. Distribution to the liver is likely mediated by LNPs entering the blood stream. The luciferase expression at the injection sites dropped to background levels after 9 days.

The distribution of a LNP with a comparable lipid composition to BNT162b2 but with a surrogate luciferase RNA (monitoring the 3H-CHE lipid label), was investigated in blood, plasma and selected tissues in male and female Wistar Han rats over 48 hours after a single IM injection at 50 µg mRNA/animal. The greatest mean concentration of LNP was found remaining in the injection site at each time point in both sexes. Outside the injection site, low levels of radioactivity were detected in most tissues, with the greatest levels in plasma observed 1 - 4 hours post-dose. Over 48 hours, the LNP distributed mainly to liver, adrenal glands, spleen and ovaries, with maximum concentrations observed at 8 - 48 hours post-dose.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of repeat dose toxicity and reproductive and developmental toxicity.

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General toxicity

Rats intramuscularly administered COVID-19 mRNA vaccine (receiving 3 full human doses once weekly, generating relatively higher levels in rats due to body weight differences) demonstrated some injection site oedema and erythema and increases in white blood cells (including basophils and eosinophils) consistent with an inflammatory response as well as vacuolation of portal hepatocytes without evidence of liver injury. All effects were reversible.

Genotoxicity/carcinogenicity

Neither genotoxicity nor carcinogenicity studies were performed. The components of the vaccine (lipids and mRNA) are not expected to have genotoxic potential.

Reproductive toxicity

Reproductive and developmental toxicity were investigated in rats in a combined fertility and developmental toxicity study where female rats were intramuscularly administered COVID-19 mRNA vaccine prior to mating and during gestation (receiving 4 full human doses that generate relatively higher levels in rats due to body weight differences, spanning between pre-mating day 21 and gestational day 20). SARS-CoV-2 neutralising antibody responses were present in maternal animals from prior to mating to the end of the study on postnatal day 21 as well as in foetuses and offspring. There were no vaccine-related effects on female fertility, pregnancy, or embryo-foetal or offspring development. No COVID-19 mRNA vaccine data are available on vaccine placental transfer or excretion in milk.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315)

2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159)

1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC)

Cholesterol

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Trometamol

Trometamol hydrochloride

Sucrose

Water for injections

6.2 Incompatibilities

This medicine must not be mixed with other medicines except those mentioned in section 6.6.

6.3 Shelf life

Unopened vial:

Frozen vial:

2 years when stored at -90 °C to -60 °C.

The vaccine may be received frozen at -90 °C to -60 °C. Frozen vaccine can be stored either at -90 °C to -60 °C or 2 °C to 8 °C upon receipt.

When stored frozen at -90 °C to -60 °C, 10-vial packs of the vaccine can be thawed at 2 °C to 8 °C for 4 hours or individual vials can be thawed at room temperature (up to 30 °C) for 30 minutes.

Thawed vial:

10 weeks storage and transportation at 2 °C to 8 °C within the 2-year shelf life.

- Upon moving the vaccine to 2 °C to 8 °C storage, the updated expiry date must be written on the outer carton and the vaccine should be used or discarded by the updated expiry date. The original expiry date should be crossed out.
- If the vaccine is received at 2 °C to 8 °C it should be stored at 2 °C to 8 °C. The expiry date on the outer carton should have been updated to reflect the refrigerated expiry date and the original expiry date should have been crossed out.

Prior to use, the unopened vials can be stored for up to 12 hours at temperatures between 8 °C and 30 °C.

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Thawed vials can be handled in room light conditions.

Once thawed, the vaccine should not be re-frozen.

Handling of temperature excursions during refrigerated storage

- Stability data indicate that the unopened vial is stable for up to 10 weeks when stored at temperatures from -2 °C to 2 °C, and within the 10 weeks storage period between 2 °C and 8 °C.
- Stability data indicate the vial can be stored for up to 24 hours at temperatures of 8 °C to 30 °C, including up to 12 hours following first puncture.

This information is intended to guide health care providers only in case of temporary temperature excursion.

Diluted medicine

Chemical and physical in-use stability has been demonstrated for 12 hours at 2 ºC to 30 ºC after dilution in sodium chloride 9 mg/mL (0,9 %) solution for injection, which includes up to 6 hours transportation time. From a microbiological point of view, unless the method of dilution precludes the risk of microbial contamination, the medicine should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

6.4 Special precautions for storage

Store in a freezer at -90 °C to -60 °C.

Store in the original package in order to protect from light.

During storage, minimise exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

For storage conditions after thawing and dilution of the medicine, see section 6.3.

6.5 Nature and contents of container

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1,3 mL concentrate for dispersion in a 2 mL clear multidose vial (type I glass) with a stopper (synthetic bromobutyl rubber) and an orange flip-off plastic cap with aluminium seal. Each vial contains 10 doses (see section 6.6).

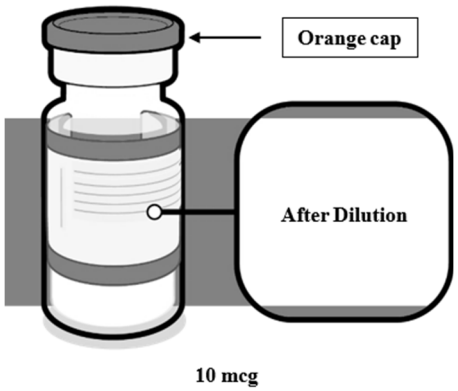
Pack size: 10 vials or 195 vials

Not all pack sizes may be marketed.

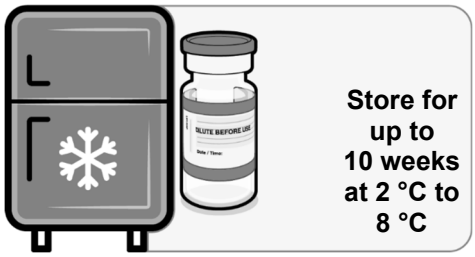
6.6 Special precautions for disposal and other handling

Handling instructions

COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE should be prepared by a health care provider using aseptic technique to ensure the sterility of the prepared dispersion.

<table>
<tr><th colspan="2">VIAL VERIFICATION OF COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION (CHILDREN 5 TO 11 YEARS)</th></tr>
<tr><td>
</td><td>• Verify that the vial has an orange plastic cap.
• If the vial has a purple plastic cap, please make reference to the professional information for COMIRNATY 30 micrograms/dose concentrate for dispersion for injection.
• If the vial has a grey plastic cap, please make reference to the professional information for COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE ADULT 30 micrograms/dose dispersion for injection.</td></tr>
</table>

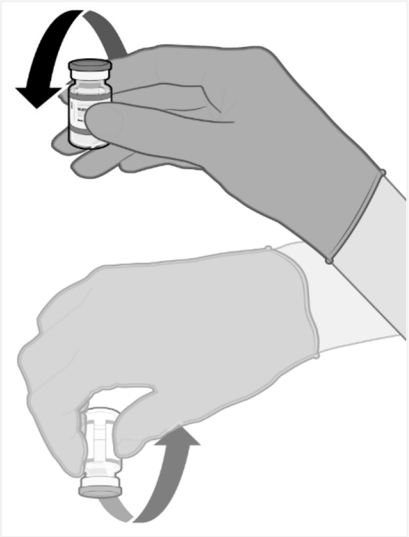
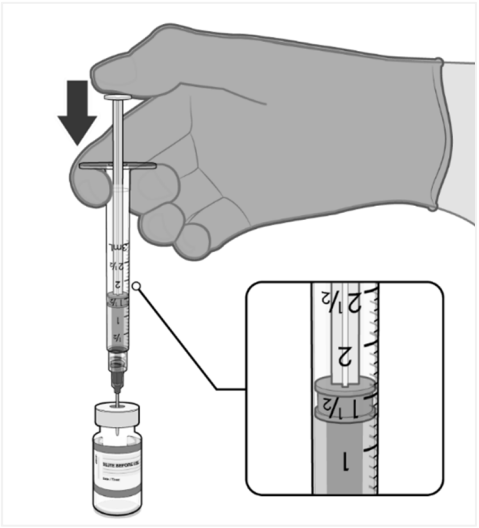
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<table>
<tr><td colspan="2">HANDLING PRIOR TO USE OF COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION (CHILDREN 5 TO 11 YEARS)</td></tr>
<tr><td>
</td><td>

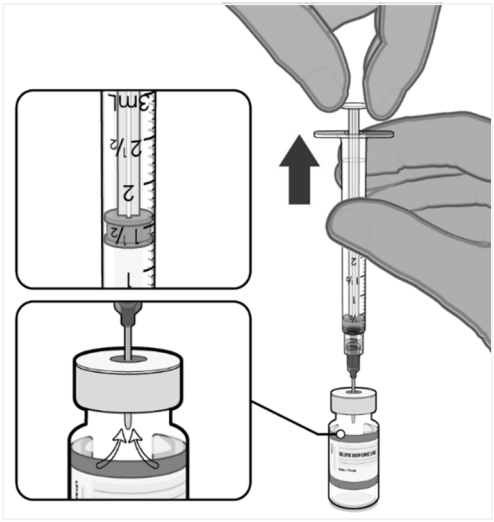
If the multidose vial is stored frozen it must be thawed prior to use. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw; a 10-vial pack may take 4 hours to thaw. Ensure vials are completely thawed prior to use.
Upon moving vials to 2 °C to 8 °C storage, update the expiry date on the carton.
Unopened vials can be stored for up to 10 weeks at 2 °C to 8 °C not exceeding the printed expiry date (EXP).
Alternatively, individual frozen vials may be thawed for 30 minutes at temperatures up to 30 °C.
Prior to use, the unopened vial can be stored for up to 12 hours at temperatures up to 30 °C. Thawed vials can be handled in room light conditions.

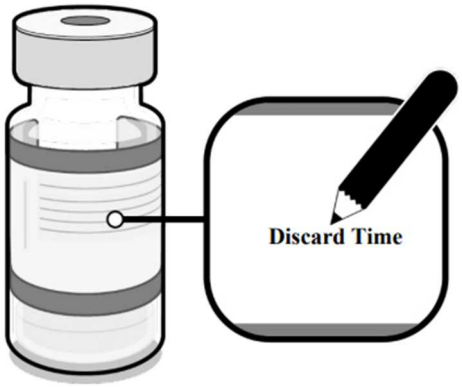
</td></tr>
<tr><td colspan="2">MIXING PRIOR TO DILUTION OF COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION (CHILDREN 5 TO 11 YEARS)</td></tr>
</table>

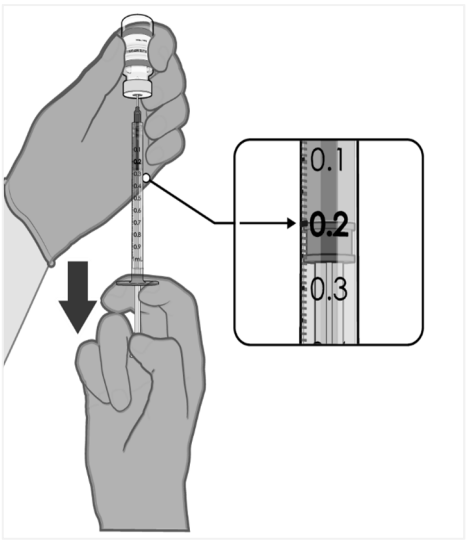
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 **Gently × 10**	• Allow the thawed vial to come to room temperature and gently invert it 10 times prior to dilution. Do not shake. • Prior to dilution, the thawed dispersion may contain white to off-white opaque amorphous particles.
DILUTION OF COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION (CHILDREN 5 TO 11 YEARS)	
 **1,3 mL of 0,9 % sodium chloride injection**	• The thawed vaccine must be diluted in its original vial with 1,3 mL sodium chloride 9 mg/mL (0,9 %) solution for injection, using a 21 gauge or narrower needle and aseptic techniques.
	• Equalise vial pressure before removing the needle from the vial stopper by withdrawing 1,3 mL air into the empty diluent syringe.

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 **Pull back plunger to 1,3 mL to remove air from vial.**	
 **Gently × 10**	• Gently invert the diluted dispersion 10 times. Do not shake. • The diluted vaccine should present as a white to off-white dispersion with no particulates visible. Do not use the diluted vaccine if particulates or discolouration are present.

<table>
<tr>
<td>

Record appropriate date and time.
Use within 12 hours after dilution.</td>
<td>• The diluted vials should be marked with the appropriate date and time.
• After dilution, store at 2 ºC to 30 ºC and use within 12 hours.
• Do not freeze or shake the diluted dispersion. If refrigerated, allow the diluted dispersion to come to room temperature prior to use.</td>
</tr>
<tr>
<td colspan="2">PREPARATION OF INDIVIDUAL 0,2 mL DOSES OF COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION (CHILDREN 5 TO 11 YEARS)</td>
</tr>
<tr>
<td>

0,2 mL diluted vaccine</td>
<td>• After dilution, the vial contains 2,6 mL from which 10 doses of 0,2 mL can be extracted.
• Using aseptic technique, cleanse the vial stopper with a single use antiseptic swab.
• Withdraw 0,2 mL of COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE for children aged 5 to 11 years.

Low dead-volume syringes and/or needles should be used in order to extract 10 doses from a single vial. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres.
If standard syringes and needles are used, there may not be sufficient volume to extract ten doses from a single vial.</td>
</tr>
</table>

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	• Each dose must contain 0,2 mL of vaccine. • If the amount of vaccine remaining in the vial cannot provide a full dose of 0,2 mL, discard the vial and any excess volume. • Discard any unused vaccine within 12 hours after dilution.

Disposal

Any unused medicine or waste material should be disposed of in accordance with local requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Pfizer Laboratories (Pty) Ltd

85 Bute Lane

Sandton 2196

South Africa

Tel: +27(0) 11 320 6000 / 0860 734 937 (Toll-free South Africa)

8. REGISTRATION NUMBER

57/30.2/0022.

9. DATE OF FIRST AUTHORISATION

15 November 2022.

10. DATE OF REVISION OF THE TEXT

29 December 2023.

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